

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMA S.A.,  
 SANOFI-AVENTIS U.S., LLC,  
  
                     Plaintiffs,  
  
                     v.  
  
 HOSPIRA, INC., APOTEX INC. and APOTEX  
 CORP.,  
  
                     Defendants.

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 ) Civil Action No. 07-721 (GMS)  
 ) (Consolidated)  
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**APOTEX’S MOTION *IN LIMINE* TO PRECLUDE SANOFI’S EXPERTS FROM TESTIFYING REGARDING THE COURT’S CLAIM CONSTRUCTION OF THE TERM “ESSENTIALLY FREE OR FREE OF ETHANOL” (“APOTEX MIL #5”)**

**SUBJECT TO PROTECTIVE ORDER – REDACTED**

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Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”) move the Court *in limine* to preclude Sanofi from testifying that a perfusion meets the requirements of “essentially free or free of ethanol” in claims 7 and 33 of the ‘512 patent, as such term was construed by the Court, regardless of the amount of ethanol in the stock solution from which the perfusion is made.

**FACTUAL BACKGROUND**

Sanofi’s experts have made it clear that they intend to testify that the claim requirement of “essentially free or free of ethanol” is met in a perfusion notwithstanding that the stock solution from which such perfusion is made does not meet this requirement.

**The “Essentially Free of Ethanol” Claim Term**

The “compositions” of the ‘512 patent can be either stock solutions (a concentrated formulation) or perfusions (the later diluted form of the stock solution). A key dispute during claim construction was what it means that a composition is “essentially free or free of ethanol,” as in asserted claims 7 and 33. This Court construed “essentially free or free of ethanol” as follows:

(a) for a stock solution, “no more than 5% ethanol by volume,” and

(b) for a perfusion, “the same amount of ethanol as a stock solution with no more than 5% ethanol by volume.”

(Doc. No. 153, Court’s Claim Construction Order, at 2.)

This correlation between a stock solution and perfusions makes sense. A perfusion is made by diluting the stock solution with a water-based solution, which means the stock solution and the perfusion will have the same amount of ethanol. The whole point of the disputed limitation was to limit the absolute amount of ethanol delivered to a patient. Thus, a stock

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solution with too much ethanol (i.e., more than 5%) will necessarily mean that the resulting perfusion has too much ethanol.

The Court rejected Sanofi's argument that for perfusions, "essentially free" of ethanol means "up to about 2% v/v/ (20 ml/L) ethanol." (*Id.* at 3). During the *Markman* hearing, in response to Sanofi's objection to a proposal which had defined a perfusion to mean "made from a stock solution having no more than 5% ethanol by volume," (Doc. No. 45, Sanofi's Claim Constr. Br., at 7-12), the Court removed the proposed phrase "made from" and instead adopted the following language for its construction of "essentially free or free of ethanol" for a perfusion: "the same amount of ethanol as a stock solution with no more than 5% ethanol by volume." (Doc. No. 153, Order at 2 & n.3.) Thus, the Court accepted the position that there exists a correlation between stock solutions and perfusions.

[REDACTED]

[REDACTED]

[REDACTED] Sanofi's view is that the amount of ethanol in the stock solution which is used to make a perfusion is irrelevant and the analysis of whether a perfusion meets this limitation does not depend on the stock solution from which it is made. [REDACTED]

[REDACTED]

**ARGUMENT**

**A. Claim Construction Is A Matter Of Law For The Court**

It is black letter law that claim construction is "exclusively within the province of the Court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996); *see also Genzyme Corp. v. Atrium Med. Corp.*, 212 F. Supp. 2d 292, 300 (D. Del. 2002) (same). In this case, the

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Court has construed the disputed claim term. Experts should not be allowed to testify about “claim construction positions or limitations on the claim language,” and are routinely disallowed from doing so. *Talecris Biotherapeutics, Inc. v. Baxter Int’l Inc.*, 510 F. Supp. 2d 356, 362 (D. Del. 2007).

Sanofi’s tortured view of the Court’s construction order vitiates its ruling. Sanofi fails to acknowledge the correlation between a stock solution and a perfusion made from that stock solution as mandated by the Court’s specific language. Rather, Sanofi relies on a hypothetical stock solution which can contain any amount of ethanol, even an amount greater than 5%. Sanofi’s basis for this approach is misguided.

Sanofi interprets the Court’s order regarding “the same amount of ethanol as a stock solution,” to mean that any hypothetical stock solution could be used to prepare the perfusion. (Ex. A at 75:3 -79:6.)

Such interpretation ignores the Court’s claim construction. The Court merely substituted the term “same amount as” for the term “made from” to address Sanofi’s objection regarding a process limitation. The Court’s specific language in its construction of “essentially free or free of ethanol” for a perfusion should not be ignored.

**B. Sanofi’s Experts Should Not Change Or Add To The Claim Terms**

Sanofi’s experts are not entitled to change or add to the claim terms simply to suit their arguments. The time for claim construction has passed. It is now time to apply the claims to evaluate infringement and invalidity. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc).

Sanofi cannot offer evidence or argument that contradicts the Court’s claim construction ruling of “essentially free or free of ethanol.” While Sanofi has seemingly accepted the Court’s

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definition for stock solutions, [REDACTED]  
[REDACTED]

This Court specifically rejected a construction that ignores the correlation between stock solutions and perfusions. Yet, Sanofi proposes to do just that and ignore the correlation. Thus, this Court should preclude argument and testimony that contradicts the Court's *Markman* ruling.

**CONCLUSION**

Apotex respectfully requests that the Court grant its motion and preclude Sanofi's experts from testifying that a perfusion meets the claim requirements of "essentially free or free of ethanol" regardless of the amount of ethanol in the stock solution from which it is made.

Dated: September 8, 2009

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# **EXHIBITS A THROUGH B**

**REDACTED**

**CERTIFICATE OF SERVICE**

I hereby certify that on September 8, 2009, I caused copies of the foregoing document to be served upon the following in the manner indicated:

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